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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,576	01/04/2006	Holger Richardsen	041165-9086-00	6747

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EXAMINER

YOUNG, HUGH PARKER

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/532,576

Applicant(s)

RICHARDSEN ET AL.

Examiner

Hugh P. Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date Jan. 4, 2006.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

This is the first Office action on the merits of application No. 10,532,576. There are ten claims pending, all of which are the subject of this action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Freisleben et al, in US Patent 6,316,260 B1, issued November 13, 2001 (filed on April 19, 1999 as a continuation of PCT/EP98/05264, filed on August 19, 1998).

3. Freisleben et al. teach liposomes and lipid agglomerates comprised of tetraether lipids and derivatives of tetraether lipids, to be used for transporting pharmaceutical active agents (Title and Abstract). Freisleben et al further teach the incorporation of other, conventional lipids (those not necessarily derived from Archaea or extremophile microbes) in column 6, lines 40-66 and again in lines 11-16, and lines 29-34 of column 7. It is known in the art that conventional liposomes are comprised of phospholipids such as those derived from soy or eggs, including lecithin, and DSPC and DPPC, as in the instant claims 6 and 7. It is known in the art, and Freisleben et al further teach, that the various lipid components one may choose for constructing liposomes can be combined in a range of component ratios, as stated starting in lines 66-67 of column 6 through lines 1-10 of column 7, and in their claims 23 and 26, these ranges

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encompassing in whole or in part the ratio ranges claimed in the instant claims 5 and 11. Liposomes, regardless of means and materials of construction, are made so as to serve as transporters of materials, broadly including peptides, proteins, nucleic acids and other small molecules including pharmaceutical active agents, and Freisleben et al teach the suitability of their invention, liposomes comprising tetraether lipids, for the delivery of numerous types of agents, including antibodies, hormones, lectins and interleukins (lines 4-8, column 8) which are or can be peptidic in nature, anticipating the instant claims 1, 3, 4, 9 and 10. The incorporation of the tetraether lipid described in the instant claims 6 and 7 is taught by Freisleben et al. in lines 11-24 of column 4, in their description of tetraether lipid derivatives, including those containing pentacyclic moieties incorporated into dibiphytanyl chains.

4. Claims 1, 6, 7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Elferink et al, (1994) in "Stability and proton-permeability of liposomes composed of archaeal tetraether lipids," *Biochimica Biophysica Acta* 1193: 247-254.

5. Elferink et al teach the suitability of tetraether lipids derived from Archaeal microbes for manufacture of stable liposomes (Abstract, and page 248, left-hand column, second paragraph). The presence of "GDNT" tetraether lipids in the liposomes made from Archaeal sources (page 150, left-hand column, lines 1-5) anticipates the use of GCTE lipids in the instant claims 6 and 7.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirby et al, (1999); "Liposomes" in: Encyclopedia of Controlled Drug Delivery, Volume 1, page 472.

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7. Kirby et al teach the use of ethanol, methanol and propylene glycol as adjuvants for liposome compositions (page 471, right-hand column, last paragraph, lines 1-15. They are included for both maintaining sterility (preservative) and improving the miscibility or texture of the composition.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

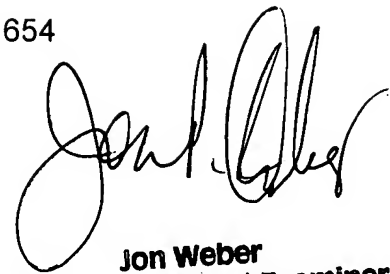
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Hugh P. Young Ph.D.

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A handwritten signature in black ink, appearing to read "Jon Weber", written in a cursive style.

Jon Weber
Supervisory Patent Examiner